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EXAMINER

QAZI, S

ART UNIT PAPER NUMBER

1616

6

DATE MAILED: 06/30/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**09/214,155**

Applicant(s)  
**Hiroaki Takayama et al.**

Examiner  
**Sabiha Qazi**

Group Art Unit  
**1616**



☒ Responsive to communication(s) filed on Dec 29, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1 and 2 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1 and 2 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 1

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **First Office Action on Merits**

**Invention:** The instant invention is drawn to a vitamin  $D_3$  derivatives having a methyl group at 2-position and 20S isomer. These compounds are useful as a treating agent for osteoporosis.

### **Status of the Application**

Claims 1 and 2 are pending in this application and are rejected for the following reasons.

### **Claim Rejections - 35 U.S.C. § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

1. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miyamoto et al. (US Patent 5,877,168). Miyamoto et al. teach vitamin D derivatives with substituents at 2b-position. See formula (I) in col. 2 and lines 33-42, where  $R_1$  represents hydrogen or a hydroxy group and  $R_2$  represents

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straight chain or branched lower alkyl group having 1-7 carbon atoms has been taught.

The instant claims differ from the reference in being stereo isomers of the US '168. Instant claims are drawn to 20S-form of vitamin D derivative of claim 1, whereas prior art teaches 20-R form.

One having ordinary skill in the art would be motivated to prepare additional derivatives of vitamin D<sub>3</sub> by modification in the structure taught by the prior art, i.e. by changing 20R-form to 20S-form because one would expect the instant compounds to possess similar properties.

The compounds of Miyamoto et al. are known to have in vitro calcium regulatory activity and differentiation stimulating activity on tumor cells, etc. and are useful as treating agent for diseases caused by abnormal calcium, such as osteoporosis and osteomalacia, or as an antitumor agent. See col. 1, lines 10-19.

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There is an ample motivation provided by the prior art to prepare such compounds when searching for new compounds of the similar activity.

Nothing unobvious is seen in substituting the known claimed isomer for the structurally similar isomer (i.e. 20S-form with 20R-form) taught by US '168 since such structurally related compounds suggest one another and would be expected to share common properties absent a showing of unexpected results.

2. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Trost M. Barry et al. (J. Am. Chem. Soc., Vol. 114, No. 25, (1992), pages 9836-45).

The reference teach a palladium-catalyzed alkylative cyclization of enynes for the synthesis of vitamin D derivatives. See scheme I, col. 1-2 on page 9837, scheme III on page 9839.

The instant claims differ from the reference by employing an analogous starting material which differs

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in having a methyl group at 4-position of the compound of formula III i.e. in instant claims 4-position is substituted by a methyl group whereas prior art teaches no substituents at this position.

The starting materials are analogous in that they are both are enynes of formula III.

One having ordinary skill in the art would have been motivated to employ the process of the prior art with the expectation of obtaining the desired product because he would have expected the analogous starting materials to react similarly.

It has been held that application of an old process to a analogous material to obtain a result consistent with the teachings of the art would have been obvious to one having ordinary skill.

#### **Data in the specification**

The data in the specification on page 39 was considered by the examiner. The comparison shows that the instant compounds (20S) are not in each case more

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active than known 20R compounds. The results are considered to be expected. Applicant is requested to provide more explanation and results in order to show unexpected results of their invention.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Objections***

Claims 1 and 2 are objected to because of the following informalities:

The brackets in claims 1 and 2 may be confusing in the printing of the patent because the text in brackets indicate the deletion of the subject matter. In order to avoid any possible confusion applicants may do appropriate correction.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



**Sabiha N. Qazi Ph.D**

**6/23/99**

**Examiner, Art Unit 1616**